The Small Entity Compliance Guide On:

Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents (21 CFR Part 897)

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The Food and Drug Administration (FDA) has prepared this guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act.

Although this guidance document does not confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents at 21 CFR Part 897.

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II. Introduction

In the *Federal Register* of August 28, 1996, the Food and Drug Administration (FDA) published a final rule to restrict the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. This rule is intended to decrease the number of children and adolescents who use cigarettes and smokeless tobacco and, by doing so, to reduce the death and disease caused by tobacco products.

FDA took this step after reviewing thousands of scientific and medical studies, reports, recommendations, and other documents, including materials received as comments on the proposed rule. FDA also studied many domestic and foreign tobacco control laws and regulations, reviewed industry documents, and received evidence and statements from former industry employees. Collectively, the evidence persuaded the agency that cigarettes and smokeless tobacco are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the act) and that regulation is necessary to restrict the sale and distribution of these products to people under 18.

This guide is designed to help you understand the rule and to explain what you should do to comply with the rule.

Before beginning our discussion of the rule and its requirements, it might be helpful for you to understand what products are covered and who is covered by the rule and how the Federal Food, Drug, and Cosmetic Act applies.

III. What and Who is Subject to the Rule?

The rule covers three general classes of nicotine-containing products: cigarettes, cigarette tobacco, and smokeless tobacco. Smokeless tobacco includes loose leaf chewing tobacco, plug chewing tobacco, twist chewing tobacco, moist snuff, and dry snuff. The rule does <u>not</u> apply to cigars, little cigars, or pipe tobacco.

The rule applies to:

* manufacturers,
* distributors, and
* retailers

who make, distribute, or sell cigarettes, cigarette tobacco, and smokeless tobacco. The guide describes the products and persons that are covered by the rule in greater detail in the discussion of the "Definitions" section below.

IV. Overview of the Federal Food, Drug, and Cosmetic Act as it Relates to Cigarettes and Smokeless Tobacco, and FDA Regulations

Regulations serve many different functions. They interpret laws passed by Congress, give instructions on how to comply with the law, explain procedures that individuals, firms, or agencies will follow, or describe obligations that those parties have.

FDA is regulating cigarettes and smokeless tobacco under its authority in the act, which is found in Title 21 of the United States Code (U.S.C.). The act gives FDA authority to regulate food, food and color additives, human and animal drugs, cosmetics, and medical devices. The agency has additional authority to regulate biological products under the Public Health Service Act.

What Are "Drugs" and "Devices?"

The act defines "drugs," in part, as “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” (See section 201(g)(1)(C) of the act (21 U.S.C. 321(g)(1)(C)).)

The act defines a "device," in part, as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory,” which is “intended to affect the structure or any function of the body of man or other animals.” (See section 201(h)(3) of the act.)

Products that meet the definition of "drug" or "device" are subject to regulation by FDA under the act. The act requires these products to comply with certain requirements, such as restrictions on their marketing or labeling, to assure their safety and effectiveness.

What is a "Combination Product?"

Some products consist of both drug and device components. For example, an inhaler used for treating asthma contains both a drug (because a drug is used to treat the asthma) and a device (because a mechanical component, known as the activator, delivers the drug to the user). Yet, in the past, FDA and companies were sometimes confused about the legal requirements for a particular combination product. Should a combination product be regulated as a drug? A device? Both?

To address this situation, Congress amended the act to clarify FDA’s authority over "combination" products. The act lets firms and interested persons ask FDA to decide how a specific combination product should be regulated. FDA can decide to assign responsibility for a combination product to a particular office and specify the regulatory controls that should be applied to that product. For example, FDA could decide to assign responsibility for a combination drug-device product to its Center for Drug Evaluation and Research (the part of

FDA responsible for human drugs), but also indicate that the regulatory controls for devices should be applied.

Here, FDA is regulating cigarettes and smokeless tobacco as combination products because they contain a drug component (nicotine) and one or more device components (the remaining parts of the cigarette or smokeless tobacco which are designed to deliver nicotine to the user).

What is a "Restricted Device?"

A "restricted device" is a device that is subject to more restrictions on its sale, distribution, or use than other devices because of its potential for harmful effect or because those additional restrictions are necessary for the use of the product. Here, cigarettes and smokeless tobacco are "restricted devices" because restrictions on the sale and distribution of these products to children and adolescents under 18 are needed to prevent young people from becoming addicted to cigarettes and smokeless tobacco in spite of their potential for harmful effects on health.

How Are Drugs and Devices Regulated?

To implement the act's requirements, FDA develops and promulgates regulations. These regulations are published as proposed rules in the *Federal Register* (FR), where they are subject to public comment. Any interested person may comment on a proposed rule, and the agency reviews each comment to determine what changes (if any) to a rule are needed. A proposed rule does not create any legally binding compliance requirements or obligations on any party.

If FDA decides to issue a final rule, it publishes the final rule in the *Federal Register* and, in most cases, also indicates when the rule will become effective. The "effective date" for a rule is the date on which the regulation requires affected firms or persons to be in compliance with the rule. A final rule does create legally binding requirements or obligations on a party.

Final rules are also published in the Code of Federal Regulations (CFR). Most FDA drug regulations are in Title 21 of the CFR, Parts 200 to 299 and 300 to 499, while most device regulations are in Title 21 of the CFR, Parts 800 to 1299.

For the rule restricting the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents, FDA published the proposed rule on August 11, 1995 (60 FR 41314). FDA published the final rule on August 28, 1996 (61 FR 44396). The rule will be codified in the CFR at 21 CFR Part 897 (see Appendix A).

Do Other Regulatory Requirements Apply to Me?

The act and FDA regulations impose additional requirements on you. For example, the act requires device manufacturers and distributors located in the United States to register their

establishments with FDA. This is done on a form FDA-2891. Manufacturers must also list the general types of devices that they sell in the United States on a form FDA-2892. (Distributors of cigarettes or smokeless tobacco are exempt from the device registration and listing requirements.) The regulations pertaining to registration and listing of establishments and products is found at 21 CFR part 807. Copies of these forms and instruction booklets can be obtained from the following offices:

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

301-443-6597 or 800-638-2041

or

Information Processing and Office Automation Branch (HFZ-307)
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

301-594-4520

Other requirements that may be applicable include:

* **general labeling requirements in 21 CFR part 801**. These requirements will specify what information must go on a device's labeling, how the information should be presented, etc. The act defines "labeling" in broad terms, such that "labeling" means all labels and "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, **or** (2) accompanying such article" (section 201(m)). **Please note that "labeling" does not have to be physically attached to a device**. For example, if a manufacturer sends printed information about a device to a consumer after the consumer has bought that device, the printed information may be considered to be "labeling."
* **device reporting requirements in 21 CFR part 803 (for manufacturers) and part 804 (for distributors).** These reports normally consist of information suggesting that a device may have caused or contributed to a death or serious injury or malfunctioned and might cause or contribute to a death or serious injury. The final rule on cigarettes and smokeless tobacco restricts these reports to information on adverse events due to product contamination, a change in any ingredient or any manufacturing process, and serious adverse events that are not

well-known or well-documented by the scientific community. (This guide discusses this requirement in greater detail in the section entitled "Miscellaneous Requirements Under Other Parts of the Rule.") However, information on where to submit these reports and what records to keep can be found in parts 803 and 804.

* **registration and listing requirements in 21 CFR part 807.** Among the provisions in part 807 is a requirement that manufacturers of restricted devices, upon FDA request, send a copy of all labeling for the device and a representative sampling of advertising. The agency, for good cause, may request a copy of all advertising for a particular device.

* **good manufacturing practice (GMP) requirements in 21 CFR part 820.** These requirements are intended to ensure that various specifications and quality controls are established for devices and that finished devices meet those specifications. Because GMP's involve manufacturing matters, manufacturers are expected to comply with the requirements. FDA published new device GMP requirements in the *Federal Register* on October 7, 1996 (61 FR 52602), and the new device GMP requirements take effect starting in June 1997. FDA has issued a helpful guidance document on the new device GMP requirements entitled "Medical Device Quality Systems Manual: A Small Entity Compliance Guide," HHS Publication FDA 96-4179.

If you have questions whether a particular FDA requirement applies to you, please contact:

Office of Policy (HF-23),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857

301-827-0867

Please note that State or local laws affect you as well. For example, your State or local government may require persons who sell cigarettes or smokeless tobacco to be a certain age or require retailers to obtain licenses to sell these products. To determine whether any additional State or local requirements apply to you, we suggest that you contact your State and local health department and law enforcement agencies. FDA's Division of Federal-State Relations (HFC-150), 5600 Fishers Lane, Rockville, MD 20857, 301-443-3360, may also be able to help you identify the appropriate State agency.

V. Regulatory Requirements Specific to the Sale and Distribution of Cigarettes and Smokeless Tobacco

Overview

The regulations at part 897 are designed to:

* reduce access to cigarettes and smokeless tobacco by persons under age 18, and
* reduce the appeal of such products to persons under age 18, through restrictions on labeling and advertising.

The regulations are NOT designed or intended, however, to restrict sales or advertising to adults.

The regulations are divided into two main parts: (1) Access, which consists largely of requirements on the sale of cigarettes and smokeless tobacco, and (2) advertising, which includes requirements for product labels, labeling, and advertising. To help you understand these requirements, this guide examines each section in the order in which it appears in part 897. [The complete text for part 897 is attached in Appendix A.]

Section-by-Section Analysis of Part 897

Subpart A--General Provisions

Subpart A consists of 3 sections: § 897.1, "Scope," which explains the scope of the rule and the possible consequences of a failure to comply with any applicable provision in part 897, § 897.2, "Purpose," which states the rule's purpose, and § 897.3, "Definitions," which defines certain terms used in part 897. Subpart A, itself, does not impose any obligations on manufacturers, distributors, or retailers, but instead provides helpful background on the rule, particularly with respect to the definitions used by FDA.

§ 897.1--Scope

Section 897.1 simply states that part 897 establishes the restrictions, under the act, on the sale, distribution, and use of nicotine-containing cigarettes and smokeless tobacco. It also explains that the failure to comply with any applicable provision in part 897 renders a cigarette or smokeless tobacco product "misbranded" under the act. "Misbranding" is prohibited under the act, as is the introduction, or delivery for introduction, into interstate commerce of any misbranded device.

Simply put, this means that if you fail to comply with a regulatory requirement that applies to you, the cigarettes or smokeless tobacco that you manufacture, distribute, or sell become misbranded. The act specifically prohibits misbranding as well as the introduction of a misbranded

product into interstate commerce, and you and the product may then be subject to regulatory action by FDA, including actions to:

* issue a warning to you and encouraging you to take voluntary corrective action before the agency begins formal legal actions to obtain compliance with the rule;
* obtain an injunction or a restraining order from a federal district court to prevent you from taking or continuing any action that would misbrand the product;
* seize the misbranded tobacco products; and/or
* seek civil money penalties against you and/or your firm
* recommend prosecution of the individuals and organizations responsible for engaging in a prohibited act and violating federal law.

§ 897.2--*Purpose*

Section 897.2 states that part 897 establishes restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products and to reduce the life-threatening consequences associated with tobacco use. The rule also applies to the sale and distribution of cigarette tobacco (because § 897.3, "Definitions," explains that the requirements pertaining to cigarettes apply to cigarette tobacco).

When FDA began drafting the rule in 1995, cigarette sales to children were illegal in all States, yet published reports in medical journals estimated that children bought millions of packs of cigarettes. Other information available to FDA indicated that most cigarette smokers started before they reached age 18, and that if a person did not start smoking by the time he or she reached 18, it would be unlikely that he or she would ever start smoking. By reducing the number of children who start smoking, the rule could lower the death rate attributed to cigarettes (approximately 400,000 Americans annually).

The rule's stated purpose also reflects a concern with smokeless tobacco use by children. FDA's review of the literature revealed that children, including children as young as 5 years old, used smokeless tobacco and contributed significantly to a revival of smokeless tobacco use in the 1980's.

§ 897.3--*Definitions*

Generally speaking, the definitions set forth in § 897.3 are self-explanatory and do not require any additional explanation in this guide. Some, such as the definitions for "cigarette" and "smokeless tobacco," are based on definitions used in other federal laws, while others, such as the definition of "manufacturer," are patterned after similar definitions in other FDA regulations.

Some definitions, however, are noteworthy because they play an important part in understanding the rule. These definitions are those that describe the types of products that are regulated, and the persons who are subject to regulation.

What Products Are Subject to Regulation Under Part 897?

The regulations apply to some, but not all, nicotine-containing tobacco products. Specifically, the regulations apply to:

* **nicotine-containing cigarettes**, which are defined as "any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of: (1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or (2) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette * * *."

In other words, a cigarette that is subject to the regulation must contain tobacco and nicotine. A product is also a "cigarette," despite any other names that may be used for that product, if it contains tobacco and nicotine, and consumers purchase that product as a cigarette.

* **cigarette tobacco**, which is defined as "any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette." Under the rule, cigarette tobacco is subject to the same requirements as "cigarettes."

Regulating cigarette tobacco is a reasonable exercise of FDA's authority. Remember that the definitions of drug and device include "components, parts, or accessories," and cigarette tobacco is a "component" or "part" of a cigarette.

* **smokeless tobacco**, which is defined as "any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity."

Smokeless tobacco is also known by several other names, including "spit tobacco" and "chewing tobacco," and there are several types of smokeless tobacco. Examples of some of the various types of smokeless tobacco are: loose leaf chewing tobacco, plug chewing tobacco, twist chewing tobacco, moist snuff, and dry snuff.

Please note that the rule does NOT make any distinction for foreign cigarettes or smokeless tobacco that are imported into the United States. If you manufacture cigarettes or smokeless tobacco or sell these products in the United States, you and your products are subject to regulation under this rule. Similarly, if you distribute or sell imported cigarettes or smokeless tobacco, you and your products are subject to regulation under part 897.

Other types of tobacco products, notably cigars, little cigars, pipe tobacco, and snuff that is inhaled through the nose (rather than placed in the mouth) are ***not*** subject to regulation under

the rule. This is because FDA had little evidence to suggest that children and adolescents use these products to any significant degree, and also because the nicotine absorption and chemistry of these products differs from that of cigarettes and smokeless tobacco.

Who is Subject to Regulation Under Part 897?

The regulations apply to three classes of persons: (1) manufacturers, (2) distributors, and (3) retailers.

Manufacturers include any person, "including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product." So, for example, if you make cigarettes, you are a "manufacturer" under the rule. Similarly, if you buy finished cigarettes and place them in other packages or relabel them, you are a "manufacturer" (because you repacked or relabeled the cigarettes) even though you did not make the finished cigarettes themselves.

FDA is aware that many distributors open each cigarette carton and affix State tax stamps on each cigarette package before resealing the carton. FDA does not consider this type of action to be "repackaging" or "repacking" that would make a distributor become a "manufacturer" under the rule. Instead, FDA interprets "repacking" or "repackaging" as the act of placing a product in a new package that differs from the package in which the product originally arrived. For example:

* if you buy cigarette cartons from company A, remove the cigarettes from company A's cartons, and repackage the cigarettes in packages that have your name (or any other name) on them, you are a "manufacturer" (because you repackaged the cigarettes).

but

* if you take company A's cigarette cartons, open each carton to place the State tax stamp on each cigarette package, and then reseal the cartons that still have company A's name (or the original brand name) on them, you are <u>not</u> a "manufacturer" because of this particular act.

Distributors include any person "who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption," but excludes "common carriers." Most distributors who are subject to regulation under part 897 will be persons who run warehousing operations and distribute cigarettes or smokeless tobacco to retailers.

To illustrate how this definition applies, if you own a warehouse and receive quantities of cigarettes and/or smokeless tobacco for sale or resale to retailers, you are a "distributor." If you

own a facility that simply opens cigarette cartons, applies tax stamps to each cigarette package, and then reseals the cartons, you may be a "distributor" under the rule (because the act of placing the stamps on the packages furthers the distribution of the product in interstate commerce). However, if you own a trucking firm and are contracted to transport cigarettes from a warehouse to a retailer, you may be a "common carrier" and might not be a distributor under the rule, even though you technically furthered the "distribution" of the product to the retailer.

Retailers are persons who sell cigarettes or smokeless tobacco to individuals for their personal consumption. This definition applies regardless of the number of products sold or the price at which they are sold. For example, even if store A generated most of its sales from selling food products and cigarettes sales represented only a fraction of total sales, the store would be a "retailer" subject to regulation under part 897. The store would also be a "retailer" regardless of whether it sold those cigarettes above cost, at cost, or below cost.

Retailers also include persons who operate facilities where vending machines or self-service displays (or merchandisers) are located, even if they do not actually own the vending machines or self-service displays themselves. (The reason for including persons who operate facilities where vending machines or self-service displays are located is described in more detail later in this guide.) Of course, the vending machine owner is also a retailer under this rule.

* * * * *

Note that the definitions of distributor, manufacturer, and retailer are NOT mutually exclusive. In other words, you can be a "manufacturer," "distributor," and a "retailer" if you engage in actions that fall within the definitions. For example, if you make finished cigarettes and sell them to individuals for personal consumption, you are a "manufacturer" (because you made the cigarettes) and a "retailer" (because you sold them to individuals for personal consumption).

Subpart B--Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

Subpart B includes the "access" restrictions in the rule and consists of four sections: (1) § 897.10, "General responsibilities of manufacturers, distributors, and retailers;" (2) § 897.12, "Additional responsibilities of manufacturers;" (3) § 897.14, "Additional responsibilities of retailers;" and (4) § 897.16, "Conditions of manufacture, sale, and distribution." The sections in this subpart limit how you can sell cigarettes or smokeless tobacco and the locations at which these products can be sold.

§ 897.10--*General Responsibilities of Manufacturers, Distributors, and Retailers*

The regulations, at § 897.10, simply state that each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco that it manufactures, distributes, or sells (or otherwise holds for sale) complies with all applicable regulatory requirements. This section is intended to remind parties that they must meet their regulatory obligations under part 897.

When FDA reviewed the comments on the proposed rule, it noticed that a large number of manufacturers' employees and retailers interpreted § 897.10 as requiring them to ensure that *other* parties complied with the rule. In other words, these comments thought--erroneously--that § 897.10 meant that retailers had to ensure that manufacturers and distributors met their regulatory obligations, that manufacturers had to ensure that distributors and retailers met their obligations, etc.

The correct interpretation of this provision is that you only have to ensure that you (and the products you have) comply with those regulatory requirements that apply to you. **However, you WOULD be subject to regulatory action if you assist another person in violating these regulations**. For example, if you are a manufacturer and supply cigarettes to a retailer whom you have reason to believe is opening the cigarette packages and selling individual cigarettes (a violation under § 897.14(d)), you would be subject to regulatory action for assisting in that violation if you continue to supply cigarettes to that retailer. Similarly, if you are a retailer, and a manufacturer or distributor asks you to distribute free samples of cigarettes or smokeless tobacco (which violates § 897.16(d)), then you would be subject to regulatory action for violating the restriction against the distribution of free samples, even though the manufacturer or distributor asked you to distribute those samples.

FDA realizes that, in situations where you know or should know that another person is violating the regulations, it may be hard to get that person to comply with the rule. The rule does not specify the course of action that you should take in such cases, but several possible options for you to consider include:

* permanently discontinuing sales, incentives, or supplies to the other party, or
* temporarily suspending sales, incentives, or supplies to the other party.

Remember, too, that the sections that are applicable to you depend largely on what you do. For example, if you make cigarettes and also sell them directly to individuals for their personal consumption, you are a manufacturer ***and*** a retailer.

§ 897.12--*Additional Responsibilities of Manufacturers*

The rule, at § 897.12, imposes an additional responsibility on manufacturers. Under this provision, a manufacturer must remove, from each retail location, all:

* self-service displays (also known as "merchandisers"),
* advertising,
* labeling, and
* other items

that the manufacturer owns and that do not comply with the requirements in part 897.

With respect to self-service displays, this means that a manufacturer must remove a self-service display that it owns from each retail location ***unless*** the self-service display is located in an establishment where no person under age 18 is present or permitted to enter at any time. (This exception is discussed in greater detail later in this guide.) In essence, the manufacturer has two options:

(1) it can physically remove the noncompliant display from the premises, or
(2) it can alter the display in a manner so that it does not violate the regulations. For example, the manufacturer could alter the display so that a person cannot take a product without the retailer's help. (However, an electronic lock or remote-operated trigger for the display is not acceptable because the display would then violate the provision requiring retailers to directly sell a product to the customer in a face-to-face exchange.) The manufacturer could move the display (with the retailer's permission) to a part of the store where customers cannot reach the product themselves.

For advertising and labeling, this provision means that the manufacturer must remove any of its own advertising that fails to comply with the requirements in subpart D, "Labeling and Advertising." For example,

* the manufacturer must remove any of its own outdoor advertising for cigarettes or smokeless tobacco that is within 1,000 feet of the perimeter of any public playground, playground area in a public park, elementary school, or secondary school.

* All other advertising or labeling must be in black text on a white background, without the use of any pictures, unless the advertising is on the cigarette or smokeless tobacco package label or is in a facility that is exempt from the "text-only" requirement because it is in an area where persons under 18 are not present or permitted to enter at any time.
* The manufacturer cannot sell or distribute nontobacco items (such as tee-shirts and hats) or services, offer any gifts in exchange for the purchase of its cigarettes or smokeless tobacco, or sponsor any athletic, musical, artistic, or other social or cultural event in the brand name, logo, symbol, or other mark of product identification that is similar or identical to that used for cigarettes or smokeless tobacco.

This guide discusses these and other labeling and advertising requirements in greater detail below.

Some commonly asked questions and answers are as follows:

Who determines whether a product is not in compliance with the regulation?

The initial determination as to whether a manufacturer-owned item complies with the regulation is made by the manufacturer itself. In most cases, this determination should be very easy to make. For example, anyone can easily determine whether a self-service display exists or whether an advertisement uses only black text on a white background.

Do I have to remove items that other manufacturers own?

When FDA reviewed the comments on the proposed rule, it noticed that many sales representatives employed by manufacturers stated that they believed that § 897.12 required them to remove items that are owned by *other* manufacturers. In fact, the *correct* interpretation of this provision leads to a different--and more reasonable--result.

Under § 897.12, a manufacturer is responsible for the items that it owns, not items owned by other manufacturers. If you work for a manufacturer and notice an item owned by another company that, in your judgment, violates the rule, *you are under no regulatory obligation to remove the violative item belonging to the other manufacturer*. In this situation, you may notify the other manufacturer about the violative item and may contact FDA (perhaps by copying FDA on your notification letter). If FDA determines that the item violates the rule, it will take appropriate action with respect to the manufacturer that owns the item.

What if I fail to remove a violative item?

If you are a manufacturer who knows that one of your items, whether it is a self-service display or piece of advertising or labeling, does not comply with the rule and you fail to remove that item, FDA may conclude that you have "misbranded" your product. You and the product

may then be subject to regulatory action (such as formal legal actions to obtain compliance with the rule, an injunction or restraining order to prevent you from taking or continuing any action that misbrands the product, seizures, and fines and imprisonment).

§ 897.14--*Additional Responsibilities of Retailers*

If you are a retailer, § 897.14 is perhaps the most important section that applies to you. This is the section that specifies your obligations to ensure that the cigarettes and smokeless tobacco that you or your employees sell are not sold to persons under age 18.

In brief, your obligations, as a retailer, are to:

* not sell cigarettes or smokeless tobacco to anyone under 18;
* verify that anyone buying cigarettes or smokeless tobacco is at least 18 years old or older. This will involve checking identification of anyone under 27 years of age showing the buyer's picture and date of birth;
* sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange between you and your customer, without the help of any electronic or mechanical device. In other words, you should see the customer with your own eyes and physically give the product to him or her. **Exception:** The face-to-face exchange requirement ***does not*** apply if the retailer is using a vending machine or self-service display in a facility where no one under 18 is present or permitted to enter at any time or where mail order sales are involved.
* not break open any cigarette or smokeless tobacco package or sell any number or quantity of cigarettes or smokeless tobacco that is less than the smallest package distributed by the manufacturer for individual consumer use. For cigarettes, the minimum package size is 20 cigarettes;
* remove or bring into compliance any violative items, such as self-service displays, advertising, and labeling, that are in the retail establishment. This requirement applies to items that you, the retailer, own, as well as to items that are in your retail establishment (whether you own them or not).

Some common issues facing retailers follow:

How do I check proof of age?

The rule requires retailers to verify a consumer's age by checking photographic identification that shows the person's date of birth. The regulation does not specify the type of photographic identification that is acceptable for verifying a person's age, but the most reliable forms of identification are cards issued by the national governments (such as military identification cards (if they contain the bearer's date of birth and a photograph) and passports), State governments (such as driver's licenses), and local governments (such as employee identification cards that contain the bearer's date of birth and photograph). Some private companies also publish guides containing photographs and descriptions of valid licenses; these guides may be helpful in distinguishing valid or genuine identification cards from fraudulent ones.

The regulations specify that you do not need to check the ID of customers who are 27 or older. But, guessing someone's age by his or her looks can be difficult. Some people simply look older than they really are. To protect you and your customers--especially your underage customers--you must ask for ID from anyone you're not sure about. However, you do not need to ask for ID from every customer every time he or she wants to purchase a tobacco product if you have already verified by means of photo ID that the customer is at least 18. In other words, if you have a regular customer whom you know is 18 or over because he or she has presented a valid photo ID in the past, you do not need to ask for proof of age every time the customer wants to buy a tobacco product.

What does FDA mean by a "direct, face-to-face exchange?"

As discussed earlier, cigarettes and smokeless tobacco are restricted devices because restrictions on the sale and distribution of cigarettes and smokeless tobacco are needed to prevent young people from becoming addicted to these products in spite of their potential for harmful effects on health. As a result, one theme in the access restrictions is to emphasize the notion that transactions involving cigarettes and smokeless tobacco should involve a sense of "formality" or gravity that conveys to both the seller and the buyer the seriousness of the transaction in which addictive and potentially lethal products are bought and sold.

The rule accomplishes this goal by requiring retailers to physically hand the product to the consumer. This means that, if you are a retailer, you and your employees must be able to:

* see the customer directly, without the use of electronic aids (such as a television screen) or mechanical devices (such as an intercom), and, when necessary, verify that he or she is at least 18 years old;
* obtain the product for the customer, and
* hand the product to the customer.

This requirement has other purposes, such as helping you verify the customer's age and reducing shoplifting.

What is a "self-service display" under the rule?

A "self-service display" is any item that permits a consumer to remove a cigarette or smokeless tobacco product without the retailer's direct assistance. Self-service displays, which are also sometimes known as "merchandisers," come in many different shapes and sizes, ranging from free-standing, multi-shelf kiosks to small display stands that are placed next to a cash register. **Regardless of the type or size, a self-service display is <u>not</u> permitted in any pharmacy, convenience store, grocery store, gasoline station, restaurant, or any other place where anyone under 18 can enter or is present at any time.**

Can I move a self-service display or vending machine to an area where I can supervise it, without having to get rid of the display or vending machine?

The short answer is, "No." Supervising a display or vending machine, using electronic locks, remote operating mechanisms, or taking other actions that continue to give customers direct access to cigarettes or smokeless tobacco products **is not permitted**. These "indirect" forms of control over displays and vending machines are often ineffective when it comes to preventing children and adolescents from helping themselves to cigarettes or smokeless tobacco.

The rule requires retailers to remove self-service displays and vending machines for cigarettes and smokeless tobacco or to move them to a place where customers are not able to help themselves to the product. Remember, if you are a retailer, the rule requires you to sell the product to the customer in a <u>direct</u>, face-to-face exchange. So, for example, if you have a small counter-top display that holds cigarette packs, you may not keep that display on the counter if customers can help themselves to the cigarettes. It does not matter whether you can see them choose the cigarettes or whether they have to "ask permission" to buy them if the customer can take the cigarettes without any action on your part.

In contrast, if you move the counter-top display *behind* the counter to an area where customers are not permitted to enter, you <u>can</u> keep the display. By moving the display out of the customer's reach, you've eliminated its "self-service" aspect.

Does the rule prohibit me from opening shipping cartons, and can I sell cigarette packages from cartons?

Section 897.14 is intended to prohibit the sale of individual cigarettes (often called "singles" or "loosies") or small quantities of smokeless tobacco. FDA reviewed several reports indicating that stores were willing to sell single cigarettes to children. Single cigarettes or small quantities of smokeless tobacco are generally cheaper than a full sized pack of cigarettes or a full-size smokeless tobacco package and, as a result, may entice children to try using these products.

Thus, under § 897.14 (and also § 897.16(b), which is discussed later), you cannot:

* break open a cigarette package or carton to sell individual cigarettes or any number less than 20 cigarettes; or
* break open a package of smokeless tobacco to sell a portion of that product.

You <u>can</u> open a shipping container in order to sell individual cartons or packages and, in the case of cigarettes, open cigarette cartons to sell individual packages.

Do I have to remove items from my store that do not comply with the regulations?

The short answer is, "Not always." If your retail establishment contains an item that fails to comply with the regulations, you have four main options. You can:

* have the item's owner remove it from your establishment;
* remove the item from your establishment yourself (particularly if it is an item that you own);
* change or fix the item so that it complies with the regulations; or
* change the item so that it does not involve cigarettes or smokeless tobacco.

For example, assume that you have a self-service display rack where the shelves have stickers or strips that identify individual cigarette brands. This item would violate the rule against self-service displays (unless your establishment qualified for the narrow "adults-only" exception), and to correct the problem, you could remove the self-service display from your store, move it behind the counter so that it is no longer "self-serve," or paint over the cigarette brand stickers and use the shelves for storing a nontobacco product.

Bringing an item into compliance with the regulation or changing its function so that it no longer involves cigarettes or smokeless tobacco might save you money, too. For example, it might be easier to use a self-service display for a product other than cigarettes or smokeless tobacco than to remove the display.

Remember: the rule also requires manufacturers to remove items that they own if those items violate the rule. So, if you think that a manufacturer owns an item in your store and that item violates the rule, you might want to contact the manufacturer and ask it to remove the item or bring it into compliance. If the manufacturer declines to remove an item that it owns, you

may have to remove the item yourself or bring it into compliance.

If you do not know who owns the item, you may have to remove the item yourself or bring it into compliance. **However, we strongly recommend that you try to determine who owns the item first**--State or local laws might make you liable if you destroy another person's property.

In short, you do have several options under the rule, and you can choose the option that you feel is most appropriate for you and your store.

Am I responsible for the actions of my employees?

Generally, Federal courts have held that employers are responsible for their employees' actions. This is true even if the employer did not know about the employee's actions or where the employee failed to take corrective action as requested by his or her employer. As an employer, you are generally responsible for the actions of your business, whether it is in the manufacturing, distributing, or retail sector, and this includes being responsible for the acts of people who work for you.

So, to avoid causing unintended violations, you should take appropriate steps to train or educate your employees to check photographic identification for proof of age and to know that the rule prohibits sales to anyone under 18 and to inform them of the other requirements in the rule. If your State or local government has additional requirements, you might want to add them to your training program, too.

§ 897.16--*Conditions of Manufacture, Sale, and Distribution*

Section 897.16 creates several different regulatory requirements. Some, such as the restriction on product names and the restriction on "impersonal" modes of sale, apply only to manufacturers or to retailers, while others, such as the minimum package size for cigarettes, apply to manufacturers, distributors, and retailers.

§ 897.16(a)--*Restriction on Product Names*

In brief, this section prevents a manufacturer from taking the brand name for a nontobacco product and using it as the trade or brand name for a cigarette or smokeless tobacco product. For example, if you are a manufacturer, you cannot take the brand name for a candy bar and use it on a cigarette or smokeless tobacco product.

There is a very limited exception to this rule. The exception applies to those brand names that were on a nontobacco product ***and*** on a tobacco product that were sold in the United States on January 1, 1995. FDA wrote this exception into the rule because it knew that there were at least three cigarette brands that shared the same name as a nontobacco product and one

smokeless tobacco brand that used the same corporate name as that used on food products. FDA created this exception to avoid hardship on those existing brands.

If you are a manufacturer and you believe that your product qualifies for the exception, you should assemble records to demonstrate that the brand name you are using existed on nontobacco and tobacco products sold in the United States on January 1, 1995. If there is any question about whether your product qualifies for the exception, these records will help FDA determine whether your product falls within the exception.

§ 897.16(b)--*Minimum Cigarette Package Size*

If you are a cigarette manufacturer, distributor, or retailer, the rule clearly states that the *minimum* cigarette package size must contain 20 cigarettes. Most cigarette packs sold in the United States contain 20 cigarettes, so compliance with this provision should be easy. If you make, distribute, or sell cigarette packs that contain less than 20 cigarettes, you will be in violation of this rule and will be subject to regulatory action.

This provision exists because studies and reports indicate that small cigarette packs--which can contain anywhere from 8 to 18 cigarettes and are commonly known as "kiddie packs"--are very popular with young children, partly because they are less expensive than full-size packs and because they are easier for children to hide. As a result, FDA created a minimum cigarette package size of 20 cigarettes.

Some commonly asked questions are:

Do I have to inspect each package to make sure it contains 20 cigarettes?

If you are a distributor or retailer, FDA does not expect you to open each cigarette pack to check whether it contains 20 cigarettes. You can rely on the manufacturer's claim that the pack does, indeed, contain 20 cigarettes.

If you are a manufacturer, you should have, as part of your GMP program, a quality control and quality assurance program so you can be sure that your products meet their desired specifications. Additionally, FDA's labeling regulations at § 801.62 require each package to bear "a declaration of the net quantity of contents." So, not only is it good manufacturing practice to make sure that the cigarette packs that you make contain 20 cigarettes, FDA's device labeling regulations require you to declare how many items are in each package. If your cigarette packs fail to contain at least 20 cigarettes in each pack, FDA may find your packages to be misbranded and take regulatory action against you.

Is there a <u>maximum</u> package size?

The regulations at part 897 do not include a maximum package size for cigarettes.

What is the minimum package size for smokeless tobacco?

The regulations do not contain a minimum package size for smokeless tobacco.

Is there any exception to the minimum package size?

There is a very <u>limited</u> exception, and it applies <u>only</u> to <u>packaged</u>, single cigarettes that are sold in vending machines that are located in places where no one under 18 is present and is not permitted to enter at any time. Very few machines will qualify for this exception.

§ 897.16(c)--*Vending Machines, Self-Service Displays, Mail-Order Sales, and Other "Impersonal" Modes of Sale*

If you are a retailer, you should remember that the regulation requires you to sell cigarettes or smokeless tobacco to your customers in a direct, face-to-face exchange, without the use of any electronic or mechanical device. This section reinforces this requirement by prohibiting retailers from engaging in "impersonal" modes of sale. **There are, however, several important exceptions.** These exceptions are:

* **mail-order sales**, but this does **<u>not</u>** allow the redemption of coupons through the mail or the distribution of free samples through the mail. By "mail order sales," the rule is limited to transactions that are completed through mail services (such as the U.S. Postal Service or any delivery service). The regulation does not require that the entire transaction be completed through the mail (although many offers to sell cigarettes or smokeless tobacco originate through the mail), but the delivery of the product must occur through the mail in order to qualify for the exception.

  FDA created this exception because there was insufficient evidence showing that children and adolescents used mail order sales to any significant degree. Additionally, several mail order retailers demonstrated that children and adolescents do not use their services, either because the minimum mail order required by their companies would be too expensive or the quantities too large for children to use.

  Note, however, if you are a mail order retailer, it is YOUR responsibility to ensure that mail order sales to people under 18 do NOT occur. FDA intends to monitor mail order sales and, if the evidence suggests that people under 18 are using mail order sales to buy cigarettes

and smokeless tobacco, FDA may take steps to restrict or eliminate this exception.

* **vending machines and self-service displays in facilities where no one under 18 is present or permitted to enter at any time**.

  Under this exception, a retailer can have a cigarette or smokeless tobacco vending machine or self-service display ONLY IF:
  - NO ONE under 18 is present in the facility at any time, or
  - NO ONE under 18 is permitted in the facility at any time.

The purpose of this exception is to allow retailers to use vending machines and self-service displays if their retail facility - whether it is a bar, a private club, or a factory - is off limits to and actually excludes anyone under 18 at all times. FDA created this exception because it recognized that some places prohibit entry by people under 18.

Some commonly asked questions about the exception are as follows:

How do I prevent people under 18 from entering my facility?

The rule does not specify how you must prevent people under 18 from entering your facility at any time--that is left up to you. One approach you might want to use includes having an employee check for proof of age at the door; if the customer is over 18, he or she can enter the facility. If the customer is under 18, he or she must be barred from entering the premises. But, regardless of the approach you use, if you want to qualify for the exception, it is important that no one under 18 be present or permitted in the facility at any time. This means that you cannot permit anyone under 18 from entering your retail facility, even for a moment.

What does the word, "facility," mean?

Generally, the word "facility" refers to the entire retail establishment. So, for example, if you operate a bar that is also connected to a restaurant, and people under 18 can eat at the restaurant, then your bar does not qualify for the exception even if people under 18 cannot go to the bar. The exception is very narrow - it only applies to places that are *entirely* off limits to people under 18 at *all* times.

There are limits to the exception. For example, if you own a factory and there are 10 buildings on the factory grounds, but you only want to put a cigarette vending machine in one building, it would not be reasonable to require you to make sure that people under 18 are not present or permitted to enter in all 10 buildings. You'd only be expected to keep people under 18 from being present or entering the building that contains the vending machine. Similarly, you are not expected to be responsible for things outside your retail establishment. For example, if you rented a store on the ground floor of a public building and the main entrance to the building is

separate from the entrance to your store, you would only be expected to keep people under 18 from being present or entering your store in order to qualify for the exception; you would not have to try to keep them from entering the rest of the building.

Can I let people under 18 into my facility on special occasions?

FDA recognizes that some facilities, such as clubs or recreation halls, might be "off-limits" to people under 18 most of the time, but that they are occasionally rented for parties or other social events where people under 18 may be present. Nevertheless, the rule is quite clear -- if the facility has a cigarette or smokeless tobacco vending machine or self-service display, no one under 18 can be present or be permitted in the facility at *any* time, even on special occasions. If you operate a facility and people under 18 are permitted to enter, you will no longer qualify for the exemption.

Who is responsible for a vending machine in a facility?

FDA recognizes that the person who operates a facility might not be the same person who owns a vending machine. Yet, if you want a vending machine in your facility, you--whether you own, rent, or otherwise operate the facility -- are responsible for ensuring that no one under 18 is present or is permitted to enter the facility at any time. The rule considers you to be a "retailer" for purposes of this exception.

Note, too, that the person who owns the vending machine is also considered to be a retailer under the rule.

§ 897.16(d)--Free Samples

The section on free samples is very clear. No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco. This restriction applies regardless of your location and regardless of whether you operate a mail order business. **There are no free samples under any conditions**.

FDA prohibited the distribution of free samples because the evidence showed that, despite voluntary industry restrictions on the distribution of free samples and despite State or local laws that restricted the distribution of free samples, significant numbers of children were able to get free samples. Consequently, the only effective means of keeping free samples away from children and adolescents was to prohibit them altogether.

§ 897.16(e)--Restrictions on Labels, Labeling, and Advertising

This section is intended to remind manufacturers, distributors, and retailers that they must comply with the requirements pertaining to labels, labeling, and advertisements in subparts C and D of part 897. (Subparts C and D of part 897 are discussed later in this guide.) Otherwise, if the labels, labeling, or advertising for your cigarettes or smokeless tobacco fail to comply with subparts C and D of part 897, you are not supposed to sell or distribute, or cause to be sold or distributed, those products.

Obviously, if you are a distributor or retailer, you do not have much control over the package labels or labeling--that is usually the manufacturer's responsibility. But, if the manufacturer prints labels that do not comply with the regulation, the products that carry the wrong labels may not be sold or distributed. Those products are considered to be "misbranded" under the act. If you think that a product's label, labeling, or advertising does not comply with the rule, you should return it to the manufacturer or distributor and ask for products that comply with the rule.

Subpart C--Labels

Under the act, the word, "label," means "a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of [the Federal Food, Drug, and Cosmetic Act] that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper" (section 201(k)).

Subpart C consists of two sections, and both apply primarily to **manufacturers** (because they are usually the only parties that put labels on products). These sections require a label to carry the product's established name and a statement of intended use. [Similar requirements exist for all drugs and devices regulated by FDA.]

§ 897.24--Established Names for Cigarettes and Smokeless Tobacco

The act requires an "established name" on the label for each drug and device. The "established name" is usually the official name that is designated for the product or the common or usual name for the product. The idea behind an established name requirement is to reduce potential confusion among firms, health professionals, and consumers by using the same name for the same product or class of products. Here, FDA chose the common or usual names for these products as the established names for cigarettes and smokeless tobacco, and these names are:

* Cigarettes
* Cigarette Tobacco
* Loose Leaf Chewing Tobacco
* Plug Chewing Tobacco
* Twist Chewing Tobacco
* Moist Snuff
* Dry Snuff

The label on each product must bear the established name that is appropriate for that product. You cannot decide to call your cigarette or smokeless tobacco product by a different name or use a different established name.

The act also requires the established name for restricted devices to be "printed prominently and in type at least half as large as that used" for any brand name or proprietary name. So, for example, if the brand name is printed in letters that are 1" high, the established name must be at least 1/2" high. (However, as explained below, FDA will refrain from taking regulatory action against a label under the established name provision if the label complies with regulations enforced by the Bureau of Alcohol, Tobacco, and Firearms (BATF).) Additionally, the established name must be "printed prominently;" it may not be printed in a manner that is difficult to see or that is hidden from view.

Some products might be so small that printing the established name in type that is one-half the size as the largest print would result in very small or illegible text. If you think this may be the case with your product, FDA encourages you to contact the agency to see what changes (if any) are needed.

§ 897.25--Statement of Intended Use and Age Restriction

The act also requires labels for restricted devices to carry a statement of intended use. Here, FDA concluded that cigarettes and smokeless tobacco are used to deliver nicotine to the body. As a result, the statement of intended use for these products is, "Nicotine-Delivery Device for Persons 18 or Older." This statement also reflects the fact that these products can be sold only to people who are 18 years old or older. The statement of intended use must appear on every cigarette and smokeless tobacco package. There are no exceptions to this requirement.

* * * * *

Now that you know about the established name and statement of intended use requirements, you may be wondering, "***How do I comply with the label requirements?***"

For cigarettes, FDA recognizes that BATF regulations require the word "cigarettes" to appear on the package and also require disclosure of the number of cigarettes in the package. FDA will consider cigarette packages that comply with the BATF regulations to be in compliance with FDA's statutory and regulatory requirements for "established names" (see §§ 801.61 and 897.24) and the "declaration of net quantity of contents" (see § 801.62; section 502(b)(2) of the act (21 U.S.C. 352(b)(2))).

As for the statement of intended use for cigarettes, the statement should appear on the "principal display panel" of the package. In brief, the "principal display panel" for a device sold over-the-counter is the part of the package label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale (see § 801.60). The principal display panel for cigarette packs or cartons will be either one of the two largest panels of the pack or carton. For cigarette packs, the statement of intended use should be at least in 10-point type or in a size equivalent to that used to display the Surgeon General's warnings. For cigarette cartons, the statement of intended use should be at least in 12-point type or in a size equivalent to that used to display the Surgeon General's warnings. For both packs and cartons, the statement should be displayed in color clearly contrasting with the color of the background (such as black text on a white background), and in the same type style or font as that used for the Surgeon General's warning, or in another type style or font of comparable legibility.

Subpart D--Labeling and Advertising

Subpart D, "Labeling and Advertising," contains three sections: § 897.30, "Scope of permissible forms of labeling and advertising;" § 897.32, "Format and content requirements for labeling and advertising;" and § 897.34, "Sale and distribution of nontobacco items and services, gifts, and sponsorship of events." If you promote cigarettes or smokeless tobacco, the requirements in this subpart will affect how you prepare your labeling and/or advertising.

It is important to remember that "labeling" includes a broad range of materials. "Labeling" includes "written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article" (section 201(m) of the act). As a result, some things that you might consider to be "advertising," such as a pamphlet or flyer that you distribute along with a product, might really be "labeling" under the act (because, in this example, it would be written, printed, or graphic matter accompanying the product).

In fact, because the act's definition of "labeling" is similar to what most people would consider to be "advertising," FDA decided to regulate labeling and advertising under the same subpart. [For other FDA-regulated products, regulations pertaining to labeling often appear with regulations directed at product labels; here, the rule specifically excludes cigarette and smokeless tobacco package labels from the requirements in subpart D.]

§ 897.30--Scope of Permissible Forms of Labeling and Advertising

Section 897.30, in essence, tells you what forms of labeling and advertising are covered under the rule. You can advertise or distribute labeling that uses a cigarette or smokeless tobacco brand name (or any other indicia of tobacco product identification) in or on:

* newspapers
* magazines
* periodicals or other publications (whether periodic or of limited distribution)
* billboards, posters, and placards; **however**, these forms of outdoor advertising may not be located within 1,000 feet of the perimeter of any public playground or playground area in a public park, elementary school, or secondary school
* nonpoint-of-sale promotional material, including direct mail
* point-of-sale promotional material, and
* audio or video formats delivered at a point-of-sale.

The "point-of-sale" is any location at which a consumer can purchase cigarettes or smokeless tobacco for his or her own consumption. In other words, a point-of-sale does not have to be fixed in one location or the same location (although most points-of-sale will probably be fixed structures, such as stores). If you sold cigarettes from a truck, your truck would be a point-of-sale.

§ 897.30(b)--The Restriction on Outdoor Advertising

Please note that the rule does limit outdoor advertising for cigarettes and smokeless tobacco. You <u>cannot</u> have an outdoor advertisement (e.g., billboard, poster, placard, transit poster), <u>regardless of its size</u>, if that advertisement is within 1,000 feet of the perimeter of any public playground, playground area in a public park, elementary school, or secondary school. Similarly, you cannot put a small poster outside your store if that poster would be within 1,000 feet of an elementary school.

FDA created this restriction because children spend a lot of time in playgrounds and schools and should be protected from cigarette and smokeless tobacco advertising when they are at these places. Determining the 1,000 foot area, however, may be a difficult task. The boundary line for a playground or school may be irregular, and boundaries may overlap (particularly in cities where parks and schools may be near each other). Nevertheless, to determine whether your advertisement, labeling, or business falls within the 1,000 foot boundary of any playground or school, here are some suggestions:

* to get a rough idea about the areas where outdoor advertisements are not permitted, you could use maps that are specific to your city or town and locate all schools and playgrounds. Then, using a ruler and the scale drawn on the map, you can measure a 1,000 foot distance from each school and playground. One helpful source of maps is the United States Geological Survey (USGS); the USGS has prepared maps for every city in the contiguous United States (that is, all States except Alaska and Hawaii), and these maps identify schools and playgrounds. (The only exceptions would be schools and playgrounds that came into existence after the map was made.) These maps can be purchased from the USGS, and you can contact the USGS by calling 1-800-USA-MAPS.

  Please note that this approach will only give you a rough idea of the areas where outdoor advertisements are not permitted. This is because most maps do not show property lines, and the rule measures the 1,000 foot distance from the <u>perimeter</u> of the school or playground. To get a precise measurement of property lines, you may need to contact your local planning or zoning commission or agency or court (if property line information is placed there).

* perhaps the most precise method, if you have a specific outdoor advertising location in mind and want to know whether it is within 1,000 feet of the perimeter of a playground or school, is to have a surveyor make that determination for you. A surveyor will be able to measure accurately the distance from the outdoor advertisement to the property line of the school or playground.

* other services, such as map-making or engineering companies, may be able to help you determine whether a particular location is within 1,000 feet of the perimeter of

a school or playground.

Please note that the above approaches are merely suggestions; you are not required to use any of them. However, if you do have an outdoor advertisement, you are responsible for ensuring that the outdoor advertisement is not within 1,000 feet of the perimeter of a school or playground.

§ 897.30(a)(2)--What to Do If You Want to Use a New Form of Advertising or Labeling That Is Not Listed in § 897.30

Section 897.30 applies regardless of whether you are a manufacturer, distributor, or retailer. In developing this section, FDA listed all types of tobacco advertising and labeling about which it knew. If you want to distribute advertising or labeling in a medium that is not listed above, you must notify FDA 30 days before distributing that advertising or labeling in that medium. The rule requires you to describe the medium that you intend to use and to discuss the extent to which the advertising or labeling may be seen by people under 18. (Any data or evidence that you can provide as support will be particularly helpful because it will help FDA determine how these regulations apply to you.) The notice should be sent to:

Office of Policy (HF-23)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

§ 897.32--Format and Content Requirements for Labeling and Advertising

§ 897.32(a)--*What Are the Format Requirements for Printed Advertising and Labeling?*

The basic requirement, under § 897.32, is that all printed advertising and labeling must use only black text on a white background. This is true regardless of how large or small the advertising or labeling is or whether it is located inside or outside your business. So, for example, if you advertise cigarettes or smokeless tobacco on a billboard, it has to use black text on a white background. If you advertise cigarettes or smokeless tobacco in your store window, that advertisement must only use black text on a white background. The rule does not permit the use of colors, pictures, symbols, drawings, or anything other than black text on a white background.[1] This is known as "text-only" advertising.

The reasons why FDA requires "text-only" advertising and labeling is that studies and reports show that children and adolescents are attracted to cigarette and smokeless tobacco advertising and labeling because the advertising and labeling convey images of a particular

[1] The rule also should not be interpreted as permitting a person to create pictures or images by selective placement of words or letters.

lifestyle, sophistication, or rebelliousness that the children and adolescents want for themselves. These studies and reports also indicate that the abundance of such advertising and labeling contributes to belief among children and adolescents that cigarettes and smokeless tobacco are not very dangerous to health or that their use is higher than it actually is. Advertising affects children's purchasing decisions, too; the U.S. Centers for Disease Control and Prevention found that 86 percent of the children who buy their own cigarettes often buy three particular brands. These three brands are the three most-heavily advertised brands.

Yet, FDA also found that children are not attracted to "text-only" advertising and labeling, while adults, who are less influenced by the imagery presented in advertising and labeling, focus on the textual information presented in an advertisement. So, by requiring "text-only" advertising or labeling, the rule should result in advertising and labeling that can convey important information to adults, but does not appeal to children and adolescents.

There are two limited exceptions to the "text-only" format requirement. If you advertise or distribute labeling in a facility where no one under 18 is present or permitted to enter at any time, then your advertising and labeling may include colors, pictures, etc. Basically, these locations will be wherever a vending machine or self-service display is permitted under the rule (see the discussion for § 897.16, "Conditions of manufacture, sale, and distribution," above).

The other exception is for "adult publications." FDA made this exception because it concluded that advertising in a publication that is read primarily by adults will have little effect on children and adolescents. The rule describes an "adult publication" as a newspaper, magazine, periodical, or other publication:

* whose readers under 18 years of age make up **15 percent or less** of the **total readership**, as measured by competent and reliable survey evidence, **and**
* is read by **2 million or fewer** people under 18, as measured by competent and reliable survey evidence.

Note that the "adult publication" exception focuses on readership instead of "subscriptions." Readership is a more accurate method for determining whether children or adolescents read a publication than subscriptions (because few children subscribe to a publication).

So how can you tell whether a particular publication is an "adult publication?" There are services that conduct readership surveys, and the results of these surveys may tell you whether a specific publication qualifies as an "adult" publication. If you choose to have a survey done, you should know that the agency will accept the age range between 12 and 17 years as a standard for determining whether people under 18 read a particular publication and that the survey should cover more than one issue of a publication. FDA is also available to work with you in developing a methodology that will determine readership. Of course, the rule always lets you use black on white "text-only" advertising and labeling in a publication regardless of whether it is an “adult

publication" or not.

§ 897.32(b)--*What Are The Format Requirements for Audio and Visual Advertising and Labeling Delivered at the Point of Sale (e.g., at a Retail Store)?*

The requirements for audio and visual advertising and labeling delivered at a point of sale are similar in concept to those for printed advertising and labeling. Audio advertising and labeling (basically advertising and labeling that is heard by consumers) must be limited to words only; that is, you cannot play music or use sound effects as part of the advertising or labeling.

Visual advertising and labeling (advertising and labeling that consumers can see, with or without sound) is restricted to black text on a white background. No colors, pictures, symbols, or other graphics are permitted. If the visual advertising or labeling is accompanied by sound, the audio portion is limited to words only; there cannot be any music or sound effects as part of the audio portion.

§ 897.32(c)--*What Statements Are Required to be in All Cigarette and Smokeless Tobacco Advertising and Labeling?*

All advertising and labeling, whether in print, audio, or visual form, must include the product's established name and a statement of its intended use.

You may recall that the rule (at § 897.24 in subpart C) already tells you what the established names for these products are. In brief, the established names for cigarettes and smokeless tobacco are:

* Cigarettes
* Cigarette Tobacco
* Loose Leaf Chewing Tobacco
* Plug Chewing Tobacco
* Twist Chewing Tobacco
* Moist Snuff
* Dry Snuff

Under the rule, the statement of intended use for these products is "A Nicotine-Delivery Device for Persons 18 or Older." This statement reflects FDA's finding that the nicotine in these products is a drug as defined in the act (because it is intended to affect the structure or function of the body). Nicotine is a highly addictive substance and causes other psychoactive effects (effects that affect the mind or behavior), such as relaxation and stimulation, and also affects weight regulation. FDA also found that cigarettes and smokeless tobacco are carefully designed products that are intended to deliver nicotine to the body. Consequently, the statement of intended use for cigarettes and smokeless tobacco reflect these findings to state that these products are nicotine-delivery devices. Furthermore, because the rule does not permit these products to be sold to

anyone under 18, the statement of intended use adds that the products are "for persons 18 or older."

The statement of intended use must follow the product's established name on all advertising. For example, the established name and statement of intended use in a cigarette advertisement is:

Cigarettes--A Nicotine-Delivery Device for Persons 18 or Older

For an advertisement on loose leaf chewing tobacco, the established name and statement of intended use is:

Loose Leaf Chewing Tobacco--A Nicotine-Delivery Device for Persons 18 or Older

Again, the product's established name and the statement of intended use must appear in every advertisement. The rule does not specify where you must place the established name and statement of intended use, nor does it specify any particular format (size, print type or font) requirement.

§ 897.34--*Sale and Distribution of Nontobacco Items and Services, Gifts, and Sponsorship of Events*

Section 897.34 establishes restrictions on three forms of promotions: (1) nontobacco items (such as hats and tee-shirts) and services (such as travel services); (2) gifts or proof of purchase giveaways; and (3) sponsorships.

§ 897.34(a)--*Nontobacco Items and Services*

The rule establishes restrictions on promotional items and services. These restrictions apply only to manufacturers and to distributors of imported products. If you are a manufacturer or a distributor of imported cigarettes or smokeless tobacco, you cannot:

* market
* license
* distribute
* sell
* or cause to be marketed, licensed, distributed, or sold

any nontobacco item or service that bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification that is the same or similar to, or identifiable with, that used for cigarettes or smokeless tobacco.

So, for example, if you made a cigarette product called "John Doe Cigarettes," you could not sell tee-shirts that say "John Doe Cigarettes." Neither could you sell a tee-shirt that uses the same logo as your cigarette brand or the color pattern used for your cigarette brand.

The rule does not apply to nontobacco items or services that use a brand name, logo, symbol, etc. for a nontobacco item or product. So, for example, if your tobacco company also makes baby food, you could distribute a tee-shirt with the baby food brand name on it, so long as neither shares the name of a cigarette or smokeless tobacco product.

§ 897.34(b)--*Gifts and Proofs of Purchase*

Section 897.34(b) bars manufacturers, distributors, and retailers from offering, or causing to be offered, any gift or item in exchange for purchasing cigarettes or smokeless tobacco or in exchange for proofs-of-purchase, coupons, or other evidence of a purchase. For example, you cannot have a catalog that offers merchandise in exchange for "points" or certificates.

The restriction also applies regardless of whether the customer can redeem his or her proofs-of-purchase for all or part of the gift's or item's value. For example, if you are a manufacturer, distributor, or retailer, you cannot offer to give an item away for free in exchange for a certain number of proofs-of-purchase or offer the item at a low cost in exchange for a smaller number of proofs-of-purchase.

This restriction reflects a concern with promotional items in exchange for proofs-of-purchase. Large cigarette manufacturers (as well as other companies) have had programs where consumers can collect proofs-of-purchase from cigarette packages and redeem them for merchandise (often with the brand name on the merchandise). Although these items are supposedly intended for adults over 20, many adolescents participate in these gift programs or have a promotional item themselves, and participation in such programs may make them more vulnerable to using cigarettes or smokeless tobacco themselves. Additionally, by wearing or using gifts that have a cigarette or smokeless tobacco brand name, these children or adolescents become "walking billboards" for these products and introduce such advertising in areas where advertising normally is not permitted (such as in schools).

§ 897.34(c)--*Sponsorship*

The sponsorship restriction in § 897.34(c) is broad. In brief, if you are a manufacturer, distributor, or retailer, you cannot sponsor or cause to be sponsored any:

* athletic event
* musical event
* artistic event
* social or cultural event
* entry in any event or

* team in any event

if that sponsored event, entry, or team would be in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to that used for cigarettes or smokeless tobacco.

To illustrate how this works, return to our imaginary "John Doe Cigarettes" brand. Assume that the package design for John Doe Cigarettes features a blue and gold diamond. Under § 897.34(c), the manufacturer cannot sponsor a basketball tournament if it would call the tournament the "John Doe Cigarette Tournament" or use the name "John Doe Cigarettes." It also could not sponsor a team using the "John Doe Cigarettes" name or even sponsor a team using the brand's blue and gold diamond.

The rule does permit manufacturers, distributors, and retailers to sponsor events, teams, and entries using their corporate names, so long as the corporate name was registered and in use in the United States before January 1, 1995 (and the corporate name itself does not use the brand name, logo, symbol, or any other indicia of product identification that is identical or similar to that used for any cigarette or smokeless tobacco brand). So, to continue with the "John Doe Cigarettes" example above, if the XXX Company makes "John Doe Cigarettes," the company can sponsor the "XXX Company Tournament," but if the company that made John Doe Cigarettes was the John Doe Tobacco Company, it cannot sponsor the "John Doe Tournament" (because the company name and brand name are similar if not identical).

There are, of course, some practical limitations on this rule. If someone other than a manufacturer, distributor, or retailer wanted to sponsor an event, entry, or team and had a name similar to a name used on cigarettes or smokeless tobacco, FDA would not take any regulatory action against that party. For example, assume that a company called "John Doe Cars" wants to sponsor a team and use the "John Doe" name. Even though a "John Doe Cigarette" brand exists, FDA would not prevent the car company from sponsoring a team using the "John Doe" name because, in this case, the "John Doe" name refers to the car company rather than the cigarette brand. Similarly, if there were a city named "John Doe," the rule would not prevent the city from sponsoring an event using the city's own name.

Miscellaneous Requirements Under Other Parts of the Rule

Medical Device Reporting by Manufacturers and Distributors

FDA monitors the safety of many regulated products, such as drugs and devices, through several means, including a reporting mechanism. Although clinical testing of a drug or device may reveal adverse effects associated with the use of that product, long-term adverse effects might go undetected. Additionally, sometimes adverse effects are due to problems that developed during the product's manufacture; for example, contamination can occur during product formulation, and the resulting product could cause adverse health effects. So, to monitor product safety, manufacturers (and, in the case of devices, distributors) are required to report to FDA adverse health effects that may be associated with their products. Individuals, such as physicians, can also submit these reports either directly to the manufacturer or to the agency. The agency examines these reports to see whether any new adverse effects may be linked to a product or whether an adverse effect is occurring with unusual frequency.

The act requires device manufacturers and distributors to report such information whenever they receive information suggesting that one of their products may have caused or contributed to a death or serious injury. However, for cigarettes and smokeless tobacco, there is already extensive medical literature on illnesses and diseases caused by and associated with the use of these products, so there is no need under these new regulations to require cigarette and smokeless tobacco manufacturers to report all deaths and serious injuries that the medical literature has linked or associated with cigarette and smokeless tobacco use. As a result, the rule requires manufacturers of cigarettes and smokeless tobacco to report only those serious adverse effects that are related to:

* product contamination;
* a change in any ingredient or manufacturing process; or
* any serious adverse event that is not well-known or well-documented by the scientific community. These adverse events may be sufficiently unique or unusual to require further investigation by the manufacturer and by the agency to understand whether the adverse event is truly associated with or caused by the product and to determine what steps are necessary to reduce or eliminate the likelihood of similar adverse effects in the future.

The rule requires distributors to report only those serious adverse events that may have been related to contamination.

The regulations in part 803, "Medical device reporting" and part 804, "Medical device distributor reporting," describe when and how manufacturers and distributors should report adverse event information. These reports are usually submitted to FDA on form 3500A. For further information on device reporting, you can contact:

The Reporting Systems Monitoring Branch (HFZ-533)
Division of Surveillance Systems
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

301-594-2735.

Information about the agency's medical products reporting system, called "MedWatch," can be obtained from:

MedWatch
The FDA Medical Products Reporting Program
5600 Fishers Lane
Rockville, MD 20852-9787

1-800-FDA-1088.

Two commonly asked questions are:

What is a "serious" adverse event?

A "serious" adverse event is an injury that is life-threatening, results in permanent impairment of a body function or permanent damage to body structure, or requires medical or surgical intervention by a health professional to preclude permanent impairment of a body function or permanent damage to a body structure. For manufacturer reports, "serious" adverse events include injuries that require medical or surgical intervention by a health professional to relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to a body structure.

How can you tell whether an adverse event is "not well-known or well-documented by the scientific community?"

The rule does not specify how to do this, but you do have several options. You can consult medical data bases, such as MEDLARS,[2] or commercially operated data bases to see whether there have been published reports of similar adverse events. Alternatively, because determining the type of adverse event can be difficult or require medical knowledge, you may

[2] MEDLARS Management Section, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894, 1-800-638-8480. While there is no charge for getting an account to access the MEDLARS data base, a charge is assessed for using the data base; the charge varies depending on the amount of time you spend searching the data base.

wish to consult a medical professional. Information from Federal, State, or local health departments may also be helpful, but probably will not be detailed enough to let you determine whether an adverse event is "not well-known or well-documented by the scientific community."

Effective Dates for the Rule

Certain provisions in the rule have different effective dates. This enables manufacturers, distributors, and retailers to take whatever steps they need to settle their existing business affairs, to adjust their current business operations, and to plan future business operations so as to comply with these regulatory requirements.

The rule has three different effective dates. Section 897.14(a) and (b), which prohibits sales to anyone under age 18 and requires retailers to verify (through the use of a photographic identification bearing the person's date of birth) that anyone buying cigarettes or smokeless tobacco is at least 18 years old or older, are effective on February 28, 1997.

The remaining provisions in the rule, except for § 897.34(c) (concerning sponsorship), are effective on August 28, 1997. The sponsorship provision, at § 897.34(c), is effective on August 28, 1998.

The agency has agreed to allow cigarette manufacturers to phase in new labels over time to meet requirements under § 897.24 (all cigarette packages must contain the product's established name, "Cigarettes"), § 897.25 (all packages must contain a statement of intended use: "Nicotine Delivery Device for Persons 18 or Older"), and § 801.62 (all cigarette packages must contain a statement of the net quantity). The agency will not seek to enforce these label requirements against products that are manufactured in the ordinary course of business before April 1, 1998, if cigarette manufacturers adhere to the following schedule:

- By October 1, 1997, not less than 33% of total manufacturing volume of product for the U.S. domestic market shall comply with all label requirements.

- By January 1, 1998, not less than 67% of total manufacturing volume of product for the U.S. domestic market shall comply with all label requirements.

- By April 1, 1998, 100% of product manufactured for the U. S. domestic market shall comply with all label requirements.

VI. Agency Contact

For more information, you can contact FDA by accessing the Internet, or by writing or calling FDA:

FDA's Internet address	http://www.fda.gov/
FDA's mailing address	Office of Policy (HF-23) Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857
FDA's hotline	1-888-FDA-4KIDS

VII. Technical Information

Legal Authority: The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.); the principal legal provisions authorizing the rule are sections 502 and 520 of the act (21 U.S.C. 352 and 360j).

Principal Regulatory Citation: 21 CFR Part 897

Additional Regulations: 21 CFR 803.19 (medical device reporting), 804.25 (medical device distributor reporting), 820.1 (quality system regulation)

Federal Register History:

August 11, 1995 - publication of the proposed rule (60 FR 41314) and jurisdictional analysis (60 FR 41453)

October 16, 1995 - notice of extension of the comment period for the proposed rule (60 FR 53560)

October 16, 1995 - notice of extension of the comment period for the jurisdictional analysis (60 FR 53620)

October 16, 1995 - notice of corrections to the jurisdictional analysis and appendices (60 FR 53621)

December 1, 1995 - notice of focus group findings regarding brief statements for cigarette advertisements (60 FR 61670)

December 19, 1995 - notice of corrections to the references in the proposed rule (60 FR 65260)

December 19, 1995 - notice of corrections to the references in the jurisdictional analysis (60 FR 65349)

December 27, 1995 - notice concerning FDA's procedures for handling confidential information in rulemaking (60 FR 66981)

March 20, 1996 - notice reopening the comment period for specific documents being added to the administrative record for the proposed rule (61 FR 11349)
March 20, 1996 - notice reopening the comment period for specific documents being added to the administrative record for the jurisdictional analysis (61 FR 11419)
August 28, 1996 - publication of the final rule (61 FR 44396) and jurisdictional determination (61 FR 44619)
September 9, 1996 - correction to the effective dates for the final rule (61 FR 47550)

Effective Dates:

February 28, 1997 for §§ 897.14(a) (prohibiting sales to persons under 18 years of age) and 897.14(b) (requiring retailers to verify the purchaser's age)
August 28, 1997 for all other provisions, except for § 897.34(c) (sponsorship)
August 28, 1998 for § 897.34(c) (sponsorship)

VIII. Appendix
21 CFR Part 897

List of Subjects in 21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 897 is added as follows:

PART 897--CIGARETTES AND SMOKELESS TOBACCO

Subpart A--General Provisions

Sec.
897.1 Scope.
897.2 Purpose.
897.3 Definitions.

Subpart B--Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

897.10 General responsibilities of manufacturers, distributors, and retailers.
897.12 Additional responsibilities of manufacturers.
897.14 Additional responsibilities of retailers.
897.16 Conditions of manufacture, sale, and distribution.

Subpart C--Labels

897.24 Established names for cigarettes and smokeless tobacco.
897.25 Statement of intended use and age restriction.

Subpart D--Labeling and Advertising

897.30 Scope of permissible forms of labeling and advertising.
897.32 Format and content requirements for labeling and advertising.
897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

Authority: Secs. 502, 510, 518, 519, 520, 701, 704, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360h, 360i, 360j, 371, 374, 393).

Subpart A--General Provisions

§ 897.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted.

§ 897.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

§ 897.3 Definitions.

(a) Cigarette means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) Cigarette tobacco means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) Distributor means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) Manufacturer means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) Nicotine means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or $C_{10}H_{14}N_2$, including any salt or complex of nicotine.

(f) Package means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.

(g) Point of sale means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) Retailer means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) Smokeless tobacco means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

Subpart B--Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

§ 897.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

§ 897.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

§ 897.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in § 897.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in § 897.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) Restriction on product names. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) Minimum cigarette package size. Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale. (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) Free samples. No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco.

(e) Restrictions on labels, labeling, and advertising. No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subparts C and D of this part, and other applicable requirements.

Subpart C--Labels

§ 897.24 Established names for cigarettes and smokeless tobacco.

Each cigarette or smokeless tobacco package shall bear, as provided in section 502 of the act, the following established name: "Cigarettes", "Cigarette Tobacco", "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff", or "Dry Snuff", whichever name is appropriate.

§ 897.25 Statement of intended use and age restriction.

Each cigarette or smokeless tobacco package, that is offered for sale, sold, or otherwise distributed shall bear the following statement: "Nicotine-Delivery Device for Persons 18 or Older".

Subpart D--Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane (HFD-40), rm. 17B-20, Rockville, MD 20857.

(b) No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

(c) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, advertising permitted under this subpart D, shall include, as provided in section 502 of the act, the product's established name and a statement of its intended use as follows: "Cigarettes--A Nicotine-Delivery Device for Persons 18 or Older", "Cigarette Tobacco--A Nicotine-Delivery Device for Persons 18 or Older", or "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff" or "Dry Snuff", whichever is appropriate for the product, followed by the words "A Nicotine-Delivery Device for Persons 18 or Older".

§ 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other then cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Dated: August 22, 1996.

William B. Schultz, Deputy Commissioner for Policy
David A. Kessler, Commissioner of Food and Drugs
Donna E. Shalala, Secretary of Health and Human Services

IX. Index